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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/750,079	Confirmation No. 1878
Applicant	:	Sepehr Fariabi	
Filed	:	December 31, 2003	
Title	:	HIGH STRENGTH MEMBER FOR INTRACORPOREAL USE	
Art Unit	:	3774	
Examiner	:	Paul B. Prebilic	
Docket No.	:	ACSG-66757 (G0970USC5)	
Customer No.	:	24201	May 22, 2009

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Commissioner for Patents

RESPONSE TO NOTICE OF NON-COMPLIANT

APPEAL BRIEF

Dear Sir:

Response to Notice of Non-Compliant Appeal Brief dated May 1, 2009.

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed on January 30, 2009.

INTRODUCTION

The present invention relates to a stent, and more particularly pertains to a stent that has exceptionally high strength yet has excellent ductility, properties which are typically mutually exclusive to one another. Consequently high strength stents are usually self-expanding devices while ductile materials are used for balloon expandable stents. The stent is formed by a process (e.g. cold working steps, tensioning, annealing, age hardening, etc.) that enables a particular alloy, although ductile, to be used in an **expandable** stent application, wherein the material must be plastically deformed in order to achieve its expanded state within a coronary artery. Similar alloys had previously been exclusively used in self-expanding applications. The present application, U.S. Serial No. 10/750,079 was filed December 31, 2003 and is a continuation of application that was filed 4/2/98 that issued as USPN 6,736,843, which is a continuation of an application that was filed 3/28/97 and that issued as USPN 6,482,166 which in turn is a continuation of an application that was filed 7/25/94 and that issued as USPN 5,636,641.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC. (formerly Advanced Cardiovascular Systems, Inc., the assignee of record), 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Par, Illinois 60664-3500. This application was originally assigned by the inventor, SEPEHR FARIABI to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed September 21, 1994, which was recorded by the US Patent Office on October 3, 1994 beginning at Reel 71531, Frame 0227.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

The application was originally filed with 37-85 (claims 1-36 were **canceled** by Preliminary Amendment). Claims 37-85 are currently **pending**, are under final rejection and are being **appealed**. A copy of the claims being **appealed** is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the final Office Action of October 31, 2008.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The rejected claims are all directed to an expandable stent formed of a particular metal alloy and requires such stent to be expandable to its radially expanded state within a coronary artery by plastic deformation.

Independent claim 37 is supported in the specification and drawings as follows:

37. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, # 40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable (page 8, lines 20) from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent assume the first low profile delivery configuration through compression and have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation (page 8, line 20).

Independent claim 44 is supported in the specification and drawings as follows:

44. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) generally aligned along a common longitudinal axis and formed from metallic alloy tubular member containing cobalt, chromium, and molybdenum, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27); and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable (page 8, line 20) from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery.

Independent claim 51 is supported in the specification and drawings as follows:

51. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of a metallic alloy containing cobalt, chromium, molybdenum and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), the cylindrical elements having a transverse dimension of about 0.003 inch (page 13, line 30) and generally aligned along a common longitudinal axis; and

the stent has first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable (page 8, line 20) from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation so as to be permanent (page 8, line 20).

Independent claim 52 is supported in the specification and drawings as follows:

52. A cylindrically shaped balloon-expandable stent for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

an interior chamber configured to receive an expandable member for plastically expanding the stent from a first low profile delivery configuration (Fig. 5; page 15, lines 1-2) to a second radially expanded configuration (Fig. 7; page 16, lines 2-4), the second radially expanded configuration having a diameter suitable to hold open the coronary artery; and

the stent having a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29), each cylindrical element formed from tubular member of an alloy containing cobalt, chromium, molybdenum and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), the cylindrical elements having a transverse dimension of about 0.003 inch (page 13, line 30) and generally aligned along a common longitudinal axis.

Independent claim 53 is supported in the specification and drawings as follows:

53. A cylindrically shaped balloon-expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expandable configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable (page 8, line 20) from the first low profile delivery configuration to the second radially expanded configuration, the second radially

expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation so as to be permanent, and the cylindrical elements having an undulating component (page 8, line 20).

Independent claim 62 is supported in the specification and drawings as follows:

62. A stent (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing about 28 to about 65 weight percent cobalt, about 5 to about 35 weight percent chromium, about 2 to about 40 weight percent nickel, and one alloy component selected from the group consisting of iron, manganese and tungsten (page 3, lines 15-27);

the cylindrical elements being generally aligned along a common longitudinal axis; and

the cylindrical elements having an undulating component (Fig. 13, #52; page 6, lines 20-29) which has an electrochemically polished metallic surface (page 10, line 4);

wherein the stent is plastically deformable from a first low profile delivery configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery (page 8, line 20).

Independent claim 66 is supported in the specification and drawings as follows:

66. A stent (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing about 28 to about 65 weight percent cobalt, about 5 to about 35 weight percent chromium, about 2 to about 40 weight percent nickel, and an amount of molybdenum up to about 15 weight percent, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27);

the cylindrical elements being generally aligned along a common longitudinal axis,; and

the cylindrical elements having an undulating component (Fig. 13, #52; page 6, lines 20-29) which has an electrochemically polished metallic surface (page 10, line 4); and

wherein the stent is plastically deformable from a first low profile delivery configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery (page 8, line 20).

Independent claim 77 is supported in the specification and drawings as follows:

77. A cylindrically shaped balloon-expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) generally aligned along a common longitudinal axis and formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27);

the cylindrical elements having an undulating component with an electrochemically polished metallic surface (page 10, line 4);

a biocompatible coating on the electrochemically polished metallic surface of the cylindrical elements (page 10, line 5); and

the stent is plastically deformable from a first low profile configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery (page 8, line 20);

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile configuration to the second radially expanded configuration without plastic deformation so as to be permanent (page 8, line 20).

Independent claim 82 is supported in the specification and drawings as follows:

82. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29), the cylindrical elements generally aligned along a common longitudinal axis and formed from metallic alloy containing cobalt, chromium, and molybdenum, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27);

undulations that are plastically expandable (page 8, line 20) in a blood vessel for deployment therein;

the stent having electrochemically polished (page 10, line 4) tubular internal and external surfaces and a reticulated tubular structure having bounded openings

for blood perfusion, the reticulated tubular structure having a continuum body (page 8, lines 12-15) made from tubing (page 9, lines 17-23); and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery (page 8, line 20).

Independent claim 83 is supported in the specification and drawings as follows:

83. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration (page 8, line 20), the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the stent is formed from a tubular alloy (page 9, lines 17-23) and has a smaller unexpanded diameter before plastic expansion and an expanded diameter upon plastic expansion (page 8, line 20).

Independent claim 84 is supported in the specification and drawings as follows:

84. A cylindrically shaped balloon expandable stent configured for use in a vessel (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the vessel (page 8, line 20);

wherein the stent is formed by cutting voids from a member having a surface and a thickness to form a stent having integrally interconnected struts (page 9, lines 17-23), the stent being plastically deformable inside a vessel from an unexpanded diameter to an expanded diameter to hold open the vessel (page 8, line 20).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the Final Office Action dated October 31, 2008, the independent claims were rejected as follows:

GROUND I

Claims 37-50, 53, 54, 56-76 and 82-85 were rejected under 35 U.S.C. § 103(a) as obvious over Robinson et al (USPN 5,891,193) (Exhibit 2) in view of Mayer (USPN 5,824,077) (Exhibit 3).

GROUND II

Independent claims 51 and 52 were rejected under 35 U.S.C. § 103(a) obvious over Robinson et al (USPN 5,891,193) in view of Mayer (USPN 5,824,077) as applied in Ground I and further in view of Hillstead (USPN 4,856,516) or Tower (USPN 5,217,483).

GROUND III

Claims 55 and 77-81 were rejected under 35 U.S.C. § 103(a) obvious over Robinson et al (USPN 5,891,193) in view of Mayer (USPN 5,824,077) as applied in Ground I and further in view of Bokros (USPN 4,300,244).

VII. ARGUMENT

Each and every claim calls for a balloon-expandable stent to be formed of a certain alloy wherein such alloy requires the stent to undergo plastic deformation in order to attain its expanded state within a coronary artery. The independent claims do not lay claim to the process by which such property is imparted but claim the structural characteristics that are inherent in the resulting stent.

GROUND I

The Examiner bases his rejection of the claims 37-50, 53, 54, 56-76 and 82-85 under 35 U.S.C. § 103 (a) as obvious over Robinson et al. (USPN 5,891,193) in view of Mayer (USPN 5,824,077) on a passage in the primary reference (col 5, lines 31-51) wherein the process is described by which the anchor, (which the

Examiner characterizes as a stent) is formed. More particularly, the Examiner asserts that because the anchor is formed by bending wire, the resulting structure is plastically deformable and could be expanded to a state where there would be no bends in the wire. While it is true that the wire is plastically deformable and the resulting structure is **ultimately** plastically deformable, there is no suggestion or teaching that the structure formed of the bent wire is capable of attaining its expanded configuration within the vessel for which it is configured for use (as is claimed) by plastic deformation. In view of the fact that the described anchor is a self-expanding device (col 3, lines 4-6), it is in fact its inherent elasticity that is relied upon for it to attain its expanded state within the artery. Once the device attains its expanded state (by elastic expansion), it cannot be plastically deformed to its expanded state, i.e. the state it is already in. The specific claim language is more particularly distinguishable as follows:

Independent claim 37 calls for:

"…wherein the cylindrical elements of the stent …. have an elasticity **insufficien**t to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation."

Clearly the cited reference has an elasticity that **is** sufficient to allow its expansion to the expanded configuration.

Independent claim 44 calls for:

"…the stent …. is **plastically** deformable from the first low profile delivery configuration to the second radially expanded configuration the second radially expanded configuration having a diameter **suitable** to hold open the coronary arter…"

Since the device of the cited reference elastically expands from its low profile delivery configuration to its expanded configuration, it cannot also be plastically deformable from its low profile delivery configuration to its expanded configuration and any further plastic expansion beyond its elastically expanded state would expand it (and the surrounding vessel wall) to an unsuitable diameter.

Independent claim 53 calls for:

"… the stent have an elasticity **insufficient** to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation…"

Again, since the cited reference teaches a structure that relies on its elasticity to expand the stent from its low profile deliver diameter to its expanded configuration, it clearly teaches away from the present invention.

Independent claims 62 and 66 call for:

"… the stent is plastically deformable from a first low profile delivery configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery."

Because the cited reference provides for a structure that undergoes elastic expansion from its low profile diameter to its expanded configuration it cannot simultaneously be plastically deformable from its low profile diameter to its expanded configuration.

Finally, independent claims 82, 83 and 84 both call for:

"… the stent … is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery."

Because the cited reference relies on elastic expansion to expand from its delivery diameter to its expanded configuration, it teaches away from a structure that is deformable between such diameters.

While the Examiner goes on to point out that the claimed alloy "is extremely similar" to the material listed in the primary reference and "closely related" to the material listed in the secondary reference, it is respectfully submitted that this in fact makes a case for non-obviousness. As is taught by **both** references, such alloys are for use in **self-expanding** applications due to the material's inherent elasticity. Without the proper treatment of the alloy prior to its use as is described in the patent application (e.g. cold working stages, tensioning, annealing, age hardening, etc.), it simply doesn't have the ductility that is necessary for it to undergo plastic deformation in order to expand from a delivery diameter to its expanded configuration. While the process by which such product is made is not the focus of the present patent application, the process does yield a different **structure** than what is described in the cited references. Such structure has different physical properties that unexpectedly renders a stent formed of the "similar" or "closely related" alloy compatible with balloon delivery systems.

Finally, in the "Response to Arguments," the Examiner argues that the device of the primary reference **could be** used in a coronary artery where the device is sized to expand as described. However, the cited reference teaches away from such sizing as it unequivocally calls for device to be sized so as to assume an expanded diameter that corresponds with the vessel diameter and to expand from a compressed delivery diameter by elastic expansion. Moreover, in view of the inherent elasticity of the structure that is described in the primary reference, expanding the device to "a diameter suitable to hold open the coronary artery" by plastic deformation would require its expansion to a diameter well beyond the

diameter of such artery and would therefore render it unsuitable for "use in a coronary artery" as is required by all claims.

In view of the clear and unequivocal teaching in the cited references that the "similar" alloys are for use in self-expanding applications, it is respectfully submitted that a structure formed of such alloys that requires plastic deformation to undergo expansion in a coronary artery effectively avoids obviousness.

GROUND II

In his rejection of claims 59 and 77-81 under 35 U.S.C. § 103(a) as obvious over Robinson et al (USPN 5,891,193) in view of Mayer (USPN 5,824,077)) as applied in Ground I and further in view of Hillstead (USPN 4,856,513) or Tower (USPN 5,217,483), the Examiner relies on the same two references (Robinson et al. in view of Mayer) as teaching a balloon-expandable stent that is formed of a specific alloy, despite the fact that both such references clearly and exclusively teach the use of similar alloys in self-expanding applications. In effect, the cited art teaches away from the present invention as the elasticity required for the described self-expanding applications is irreconcilable with the ductility required for balloon-expandable applications. There is no suggestion or teaching that the described elastic alloys can be rendered sufficiently ductile and thus suitable for a balloon-expandable stent. It is respectfully submitted that for the same reasons set forth in Ground I above, a balloon-expandable stent formed of such alloys effectively avoids obviousness.

GROUND III

In his rejection of claims 59 and 77-81 under 35 U.S.C. § 103(a) as obvious over Robinson et al (USPN 5,891,193) in view of Mayer (USPN 5,824,077)) as applied in Ground I and further in view of Hillstead (USPN 4,856,513) or Tower

(USPN 5,217,483), the Examiner relies on the same two references (Robinson et al. in view of Mayer) as teaching a balloon-expandable stent that is formed of a specific alloy, despite the fact that both such references clearly and exclusively teach the use of similar alloys in self-expanding applications. In effect, the cited art teaches away from the present invention as the elasticity required for the described self-expanding applications is irreconcilable with the ductility required for balloon-expandable applications. There is no suggestion or teaching that the described elastic alloys can be rendered sufficiently ductile and thus suitable for a balloon-expandable stent. It is respectfully submitted that for the same reasons set forth in Ground I above, a balloon-expandable stent formed of such alloys effectively avoids obviousness.

VIII. CLAIMS APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

XI. CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not obvious over any combination of the cited references and that the Examiner's rejections of claims 37-85 were therefore erroneous. Appellant

respectfully requests reversal of the rejections of independent claims 37, 44, 51, 52, 53, 62, 66, 77, 82, 83 and 84 as well as all claims that depend therefrom.

Respectfully submitted,

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GOH:lm

LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1.	Appealed Claims
2.	U.S. Patent No. 5,891,193, Robinson et al.
3.	U.S. Patent No. 5,824,077, Mayer